

Claims: What is claimed is:

1. An improved method of hormonal treatment of breast cancer and said hormonal treatment comprising of breast implants of anti-estrogens and steroid hormones, or its synthetic derivatives in one or more slow release formulations and permitting said drugs to be continuously released at near constant rate directly to the breast for longer periods with minimal or no systemic toxicity.
5
2. A method according to claim 1 further comprising release of said anti-estrogen and hormonal compositions to the breast for extended periods by diffusion and biodegradation from said breast implants in sufficient amounts to saturate the binding sites for said drug compositions in the breast and to exert their maximum tumor control activity.
10
3. A method of claim 1 wherein said implants comprising of hormonally effective compositions selected from the anti-estrogen groups consisting of tamoxifen, raloxifene and toremifene, and from the hormonal groups consisting of progesterones and corticosteroids.
15
4. A method according to claim 1 wherein said prostatic implants of said drug compositions are made as separate or in combination thereof.
20
5. The method of claim 1 wherein said breast implants are made as biodegradable fused combinations of said therapeutic drug compositions and a lipoid carrier and said fused implants containing a single or multiples of said drug formulations for their slow release direct to breast.
25
6. A method according to claim 1 wherein said breast implants are made of Silastic capsules containing said therapeutic drug compositions as separate or in combination thereof for said formulation's slow release direct to breast.
30

7. The method of claim 1 wherein said breast implants are made as injectable microcapsules prepared from biodegradable polymer and said microcapsules containing said therapeutic drug compositions as separate or as in combination thereof for injection to the breast as slow release implant.
- 5
8. The method of claim 7, wherein said prostatic implants are made as injectable microcapsules prepared from biodegradable polymer and said microcapsules containing said therapeutic drug compositions dispensed in sterile liquid medium in
- 10 sterile syringe for direct prostatic injection as slow release implant.
9. The method of claim 7, wherein said breast implants are made as injectable microcapsules prepared from biodegradable polymer and said microcapsules containing said therapeutic drug compositions dispensed in a mixture of sterile liquid
- 15 mediums like normal saline, a local anesthetic and ethanol in a sterile syringe for direct injection to the breast as chelating slow release formulations when it comes in contact with breast tissue.
10. The method of claim 1 wherein said breast implants are selected from readily
- 20 available commercial pharmaceutical preparations of anti-estrogens steroid hormones or their derivatives and said implants containing a single or multiples of said drug formulations for their slow release direct to the breast.
11. An improved method of concomitant hormonal and radiation treatment of the breast
- 25 cancer and said hormonal treatment comprising of breast implants of anti-estrogens and steroid hormones in one or more slow release formulations and permitting said drugs to be continuously released at near constant rate directly to the breast during the radiation therapy and afterwards for longer periods.

12. An improved method of concomitant hormonal and radiation treatment of the breast cancer according to claim 11, wherein said continued slow release of hormonal composition directly to the breast during the interstitial radioactive seeds implants and afterwards for longer periods.

5

13. An improved method of concomitant hormonal and radiation treatment of breast cancer according to claim 11, wherein said hormonal implants to the breast is performed concomitantly with the radioactive implants to improve cure and convenience to patient than when they are implanted separately.

10

14. An improved method of treating hormone dependent and hormone refractory breast cancer and its accessible metastasis by implanting combinations of hormones and anti-estrogens to said tumor sites for improved tumor control with lesser toxicity than by administering said hormonal compositions at higher doses by mouth, subcutaneous, intramuscular or intravenous routes and said hormone compositions containing in one or more slow release implant formulations.

15

15. A method of claim 14, wherein said breast, subcutaneous or intramuscular hormonal implants methods comprising implanting single or synergistic combination of hormonally and cytotoxicologically effective compositions selected from the anti-estrogen groups consisting of tamoxifen, raloxifene and toremifene and from the hormonal groups consisting of iodo-estradiol, progestones, corticosteroids and they are fused with a lipoid carrier or encapsulated in Silastic capsules or formulated as injectable microcapsules as suitable slow-release breast, subcutaneous or intramuscular implant.

20

16. A method of claim 14, wherein said slow-release breast implant of anti-estrogen and hormonal compositions for treating breast cancer and providing minimum or no toxicity as compared to when said drug compositions are administered by oral routes daily.

25

30

DRAFTS AND DRAFTING

17. A method of claim 14, wherein high concentrations of said drug composition to the
breast is achieved by implanting said formulations directly to the breast and to derive
the added beneficial effect from these breast implants on breast cancer by inhibiting
the hypothalamic-pituitary LHRH, FSH and LH secretion by these composition's
5 systemic contents.
18. Slow-release anti-cancer breast implants products for treatment of breast cancer and
comprising of anti-estrogens and steroid hormones as fused with a lipoid carrier or as
encapsulated in Silastic capsules or as injectable microcapsules and are suitable for
10 breast implantation such that said hormonally and cytotoxically effective
compositions are continuously released at relatively high constant rates to the breast.
19. The said products of claim 18 being further characterized by providing effective
tumor control and having minimum or no systemic toxicity associated with said
15 composition's breast implants than if they were daily administered orally for several
years at much higher doses to achieve the same results.
20. Slow-release anti-cancer prostate implant product of claim 18, wherein said single
drug formulation is made from any one of the anti-estrogen drugs from a group
20 consisting of tamoxifen, raloxifene or toremifene and hormonal compositions
consisting of progesterone, androgens or prednisolone.
21. Slow-release anti-cancer breast implant product of claim 18, wherein said synergistic
two drugs formulations comprises of an anti-estrogen from the groups of tamoxifen,
25 raloxifene, or toremifene and a progesterone composition selected from the group
consisting of megestrol acetate, medroxyprogesterone, norethindrone acetate or
norgestrel or from the corticosteroids groups, the prednisolone.
22. Slow-release anti-cancer breast implant product of claim 18, wherein said synergistic
30 three drugs formulations comprises of an anti-estrogen from the groups of tamoxifen,

DO NOT PUBLISH

raloxifene, or toremifene and a progesterone composition selected from the group consisting of megestrol acetate, medroxyprogesterone, norethindrone acetate norgestrel and from the corticosteroids group prednisolone.

- 5 23. Anti-cancer products of claim 18, wherein said compositions comprising of single or
synergetic combination of hormonally and cytotoxically effective amount of an anti-
estrogen from the groups of tamoxifen, raloxifene, or toremifene and a progesterone
composition selected from the group consisting of megestrol acetate,
medroxyprogesterone, norethindrone acetate norgestrel and from the corticosteroids
group prednisolone as fused with a lipoid carrier suitable for prostatic implantation.

10

24. Anticancer products according to claim 18, wherein said single or synergetic
combination of hormonally and cytotoxically effective amounts of formulations as
fused with a lipoid carrier suitable for breast implantation such that said
compositions are continuously released at relatively constant rates to the breast for
longer periods and the contents of said compositions being kept in amounts effective
to suppress tumor growth with minimum or no systemic toxicity than if said drug
compositions were administered daily by oral routes at much higher doses to achieve
the same results as by said low dose breast implants.

15

20

25

26. Anticancer products of claim 18, wherein said single or synergetic combinations of
hormonally and cytotoxically effective amounts of an anti-estrogen from the groups
of tamoxifen, raloxifene, or toremifene and a progesterone composition selected
from the group consisting of megestrol acetate, medroxyprogesterone, norethindrone
acetate norgestrel and from the corticosteroids group prednisolone in same or
separate slow release Silastic capsules suitable for prostatic implantation.

30

27. Anticancer products according to claim 18, wherein said single or synergetic
combination of hormonally and cytotoxically effective formulations as in slow
release Silastic capsules suitable for breast implantation such that said compositions

are continuously released at relatively constant rates for longer periods and with minimum or no systemic toxicity than if said drug compositions were frequently administered orally at much higher doses to achieve the same results as by said low dose breast implants.

5

27. Anticancer products according to claim 18, wherein said anti-cancer products comprising of single or synergistic combination of hormonally and cytotoxically effective amounts of an anti-estrogen from the groups of tamoxifen, raloxifene, or toremifene and a progesterone composition selected from the group consisting of megestrol acetate, medroxyprogesterone, norethindrone acetate norgestrel and from the corticosteroids group prednisolone in same or separate slow release injectable microcapsules suitable for breast implantation.
 28. Anticancer products according to claim 27, wherein said single or synergistic combination of hormonally and cytotoxically effective amount of formulations as injectable microcapsules suitable for breast implantation such that said compositions are continuously released at relatively constant rates and the contents of said compositions being kept in amounts effective to suppress tumor growth with minimum or no systemic toxicity than if said drug compositions were frequently administered orally at much higher doses to achieve the same results as by said low dose breast implants.
 29. Anticancer products according to claim 18, wherein said implant products comprising of an anti-estrogen from the groups of tamoxifen, raloxifene, or toremifene and a progesterone composition selected from the group consisting of megestrol acetate, medroxyprogesterone, norethindrone acetate norgestrel and from the corticosteroids group prednisolone and are made as separate or as mixtures of two or more thereof and fused with a lipoid carrier.

30. Anti-cancer prostatic implant products according to claim 18, wherein said
biodegradable breast implants comprising of an anti-estrogen from the groups of
tamoxifen, raloxifene, or toremifene and a progesterone composition selected from
the group consisting of megestrol acetate, medroxyprogesterone, norethindrone
acetate norgestrel and from the corticosteroids group prednisolone and are made as
separate or as mixtures of two or more thereof as injectable microcapsules.

5

31. Anti-cancer prostatic implant products of claim 18, wherein said breast implants
comprises of an anti-estrogen from the groups of tamoxifen, raloxifene, or
toremifene and a progesterone composition selected from the group consisting of
megestrol acetate, medroxyprogesterone, norethindrone acetate norgestrel and from
the corticosteroids group prednisolone and are made as separate or as mixtures of
two or more thereof in Silastic capsules.

10

15 32. A slow-release hormonal breast implant method and products comprising single or
synergetic combination of hormonally and cytotoxically effective compositions
selected from the an anti-estrogen groups of tamoxifen, raloxifene, or toremifene and
a progesterone composition selected from the group consisting of megestrol acetate,
medroxyprogesterone, norethindrone acetate norgestrel and from the corticosteroids
group prednisolone and they are fused with a lipoid carrier or encapsulated in Silastic
20 capsules or formulated as injectable microcapsules as suitable slow-release breast
implantation and implanting said products for the treatment of early and advanced
implantation and implanting said products for the treatment of early and advanced
stage breast cancers and as hormonal treatment combined with radiation.

25 33. A method and product of claim 32, wherein said hormone implant treatment of breast
cancer is less-costly, less toxic and more convenient to the patient.

34. A method and product of claim 32, wherein said slow-release anti-estrogen implant
treatment of the breast as hormonal prophylaxis against developing breast cancer by

saturation of the breast tissue's binding sites for said anti-estrogens with high efficiency than by said anti-estrogen's daily oral administration at higher doses.

5

10

15

20

25

30